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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,605	12/09/2003	David James Dooley	PC25026A	4759

28880 7590 03/07/2006

WARNER-LAMBERT COMPANY
2800 PLYMOUTH RD
ANN ARBOR, MI 48105

EXAMINER

ROYDS, LESLIE A

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/731,605	Applicant(s) DOOLEY ET AL.	
	Examiner Leslie A. Royds	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-19 are presented for examination.

Requirement for Election

This application contains claims directed to the following patentably distinct species of (a) the disorders or conditions as recited in present claims 1-14, and (b) the alpha-2-delta ligand compounds recited in claims 16-19.

The species of disorders or conditions are independent or distinct because the species of disorders or conditions are each distinct from one another in etiology, pathophysiological manifestations, treatment protocol (i.e., duration of treatment, dosage amounts of pharmaceutical agents to be administered, frequency of treatment, etc.) and patient population such that a comprehensive search of the patent and non-patent literature for any one such disorder or condition would not necessarily result in a comprehensive search of any one or more of the other disorders or conditions recited in the present claims. Notwithstanding that Applicant may have established an underlying commonality to this broad genus of disorders or conditions, namely, that each may be effectively treated with an alpha-2-delta ligand compound, it remains that the art does not necessarily recognize such a shared characteristic as being common to each of the huge number of disorders or conditions encompassed by the claims. Despite the fact that there may be incidental overlap between any one or more of the disorders or conditions contained within the claims, such does not change the fact that each of the disorders or conditions are distinct from another because they lack a common etiology, pathophysiological manifestations, treatment protocol and patient population and, therefore, are considered patentably distinct. In addition, the discovery of any one of the presently claimed disorders or conditions would not

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necessarily anticipate or reasonably suggest or render obvious any one or more of the other disorders or conditions of the present claims.

The species of alpha-2-delta ligand compounds are independent or distinct because the species of alpha-2-delta ligands recited in the present claims are each structurally, functionally and/or chemically distinct from any one other alpha-2-delta ligand recited in the present claims such that a comprehensive search of the patent and non-patent literature for any one such compound would not necessarily result in a comprehensive search of any one or more of the other alpha-2-delta ligands recited in the claims. Notwithstanding that Applicant may have established an underlying common function to a combination of this broad genus of compounds, namely, that they are capable of treating the presently claimed disorders or conditions (see present claims 1-14), it remains that the art does not necessarily recognize such a shared function as being common to each of the variety of distinct compounds encompassed by the claims. Despite the fact that there may be incidental overlap between any one or more of the compounds contained within the claims, such does not change the fact that each of the alpha-2-delta ligands encompassed by the claims are distinct from one another because they lack a common physical structure or function and, therefore, are considered patentably distinct. In addition, the discovery of any one of the presently claimed compounds would not necessarily anticipate or reasonably suggest or render obvious any one or more of the other compounds of the present claims.

Applicant is required under 35 U.S.C. 121 to elect ONE single disclosed species of disorder or condition as recited in present claims 1-14 and ONE single alpha-2-delta ligand compound as recited in present claims 16-19 for prosecution on the merits to which the claims

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shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-14, 16-17 and 19 are generic.

Applicant is advised that a reply to this requirement must include an identification of the single species of disorder or condition and the single species of alpha-2-delta ligand that is elected consonant with this requirement, identification of each moiety contained within the generic formula (i.e., R1, R2, R3, etc.) if the agent is elected from present claims 16-17 or 19, a structural depiction of the single elected species of alpha-2-delta ligand and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. Please reference MPEP §809.02(a).

A telephone call was made to Karen DeBenedictis at Warner-Lambert on Friday, March 3, 2006 to request an oral election to the above requirement for election, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

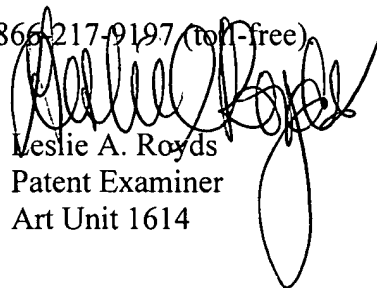
Should Applicant traverse on the ground that the inventions or species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leslie A. Royds
Patent Examiner
Art Unit 1614

March 3, 2006



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